

Protocol Evaluating the effectiveness of a school-based group programme for parents of children at risk of ADHD: the 'PArents, Teachers and CHildren WORKing Together (PATCHWORK)' cluster RCT protocol

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ABSTRACT

Introduction: Early intervention for childhood behavioural problems may help improve health and educational outcomes in affected children and reduce the likelihood of developing additional difficulties. The National Institute for Health and Clinical Excellence guidelines for attention deficit/hyperactivity disorder (ADHD), a common childhood behavioural disorder, recommend a stepped care approach for the identification and management of these problems. Parents of children with high levels of hyperactivity and inattention may benefit from intervention programmes involving behavioural management and educational approaches. Such interventions may be further enhanced by providing training and feedback to teachers about the strategies discussed with parents. In relation to children with high levels of hyperactivity, impulsiveness and inattention, we aim to test the feasibility and effectiveness of a parenting programme (with and without an accompanying teacher session) in primary schools.

Methods and analysis: This clustered (at the level of school) randomised controlled trial (RCT) focuses on children in their first four school years (ages 4–8 years) in the East Midlands area of England. Parents will complete a screening measure, the Strengths and Difficulties Questionnaire, to identify children with high levels of hyperactivity/inattention. Three approaches to reducing hyperactivity and attention problems will be compared: a group programme for parents (parent-only intervention); group programme for parents combined with feedback to teachers (combined intervention); and waiting list control (no intervention). Differences between arms on the short version of Conners' Parent and Teacher Rating Scales Revised will be compared and also used to inform the sample size required for a future definitive cluster RCT. A preliminary cost-effectiveness analysis will also be conducted.

Ethics and dissemination: The outcomes of this study will inform policy makers about the feasibility, acceptability and effectiveness of delivering targeted

ARTICLE SUMMARY

Article focus

- Pragmatic cluster randomised controlled trial (RCT) of a school-based intervention.
- Early intervention study assessing whether behavioural interventions with parents and sharing information with teachers about the behavioural strategies can help with the management and outcomes of children with attention deficit/hyperactivity disorder (ADHD)-type difficulties.

Key messages

- As recommended by the National Institute for Health and Clinical Excellence guidelines for ADHD, a stepped care approach in increasing the range of the intervention will be tested.
- The study will inform about the feasibility and acceptability of delivering an early intervention programme through schools.

Strengths and limitations of this study

- Real-world study using a cluster RCT design with cost-effectiveness and cost-utility analyses.
- The desirability and acceptability of screening and offering interventions through schools for ADHD-type problems are currently unclear.

behavioural interventions within a school setting. The study has received ethical approval from the University of Nottingham Medical School Ethics Committee.

Trial registration: ISRCTN87634685

INTRODUCTION

Improving young people's mental health and promoting healthy behaviours are key challenges for all children's services. These

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include the National Health Service and Local Authority Children and Young People's (CYP) services, which incorporate education and social care services. National service priorities in the UK reflect 'Every Child Matters', the National Service Framework for Children and the Quality, Innovation, Productivity and Prevention transformation programme, which aims to improve the effectiveness and efficiency of care.¹⁻³ Priorities reflect the need for the early identification and intervention for children with mental health problems to improve their outcomes and to ensure access to services at the most appropriate level and setting for the child and the family. The national Targeted Mental Health in Schools programme aims to ensure that all local authorities in partnership with health services develop sustainable models to implement targeted interventions locally for 5-year-olds to 13-year-olds.⁴ In relation to younger children (aged 4-8 years), we aim to work collaboratively with schools to determine how best to implement approaches for prevention, identification and early intervention that complement the work of local services. This study focuses on early identification approaches and the implementation of stepped care interventions for children with high levels of hyperactivity and inattention in community (school) settings.

ATTENTION DEFICIT/HYPERACTIVITY DISORDER

Attention deficit/hyperactivity disorder (ADHD), defined by pervasive and developmentally inappropriate levels of inattention and/or hyperactivity/impulsiveness resulting in impairment in both home and school settings, affects 3-5% of school-aged children.⁵ It often occurs alongside other childhood behavioural disorders, such as oppositional defiant disorder (ODD), has a widespread impact on the development of affected children and their families, and carries long-term implications. High levels of ADHD symptoms are a key target for early recognition and intervention in children with disruptive behavioural problems. ADHD is a treatable risk factor for the development of disruptive and antisocial behaviour, other mental health disorders, accidents, educational difficulties, expulsion from school, social exclusion, adult mental health problems, employment problems and criminality. However, only half of children and young people with ADHD are seen by specialist paediatric services or child and adolescent mental health services.⁶ Of these, many may not receive evidence-based interventions and there is likely to be considerable local variation in access to non-pharmacological interventions. For both clinically referred and unreferred children, there is strong evidence from randomised controlled trials (RCT) for the effectiveness of parent training programmes for young children with behavioural problems including ADHD.⁷ However, there is a gap in the evaluation and implementation of parenting programmes for children with features of ADHD in everyday community settings such as schools.

The National Institute for Health and Clinical Excellence (NICE) guidelines on ADHD recommend a stepped care approach for children with, or at risk of, ADHD.⁵ A prediagnostic step for children with high levels of these difficulties involves early intervention with parenting programmes. This approach may be sufficient for a proportion of children who may then not need referral to specialist services and this may also improve children's behavioural and educational outcomes. Although local authority CYP services provide some parent group interventions through Sure Start Children's Centres and some are available through the voluntary sector, their availability is sporadic. The NICE guidelines have recommended that group parent-training/education interventions become universally available for children with ADHD-type difficulties at a prediagnostic stage.

Other RCT evidence has shown that the effectiveness of parent training programmes can be enhanced through teacher training and regular updates to teachers about the strategies used with parents.⁸ This is important, as teachers are the professional group most likely to be consulted by parents with concerns about ADHD and teachers are well placed to identify which children are at risk of later problems.^{9 10} Complex interventions are necessary to achieve the broad aim of improving the identification and management in the community of young children with high levels of ADHD-type difficulties.¹¹ It has been established that components including the screening of children with high levels of ADHD symptoms in schools using parent-rated and teacher-rated scales and the delivery of teacher educational interventions are feasible in practice.¹² This study looks at how psychological treatment approaches can be introduced into schools—an everyday community setting attended by children. Such studies are required to demonstrate the acceptability, feasibility and effectiveness of the individual components of a complex intervention.

PARENTING INTERVENTIONS FOR ADHD

The NICE guidelines on ADHD included a systematic review of parenting intervention programmes for ADHD.⁵ Most existing parent-training/education programmes have been designed for children with behaviour problems in general, rather than specifically for ADHD. There is better evidence for their efficacy in helping with ADHD symptoms among preschool children. The 'New Forest Parenting Programme' has the strongest evidence of efficacy, although it has not been systematically evaluated in relation to school-age children.¹³ Programmes such as the 'Triple P—positive parenting programme' and the 'Incredible Years parent training programme' have generally been shown to be effective in relation to children with oppositional/conduct problems who also have comorbid ADHD, rather than for ADHD per se.^{14 15} A recent trial

reported some significant intervention effects for Incredible Years in a mixed community and clinical sample of children with ADHD and ADHD+ODD.¹⁶ However, this study used a very intensive version of the Incredible Years programme consisting of 40 h of intervention for parents and 40 h of intervention for the child. While Hoath and Sanders¹⁷ reported some positive intervention effects for Triple-P on behavioural problems in a small pilot study ADHD sample, they did not test intervention effects on ADHD. The '1-2-3 Magic' programme¹⁸ has some components which are specific to ADHD and has been strongly advocated by UK ADHD support groups such as the national Attention Deficit Disorder Information and Support Service. Our local mapping survey (Coates and Sayal, unpublished observations) found that it was the most commonly used programme in the region for parents of children with ADHD-type behaviour difficulties. '1-2-3 Magic' has been evaluated in a controlled before and after study.¹⁹ However, to the best of our knowledge there has not been an RCT in schools to test its cost-effectiveness for children with ADHD-type difficulties.

THE STUDY

This study aims to:

1. Deliver an early intervention group programme for parents of children at risk of ADHD and assess whether interventions for parents and sharing information about strategies used with teachers can help with the early identification and management of children with ADHD-type difficulties and are cost-effective.
2. Test the feasibility of delivering an early intervention programme through schools and its local implementation in practice.
3. Elicit the attitudes of parents, teachers and key stakeholders about the acceptability of the interventions.

We hypothesise that there will be a greater reduction in ADHD symptoms on a parent-rated and teacher-rated questionnaire in children whose parents and teachers receive a combined intervention compared to a parent-only intervention arm and no intervention (control) arm. We also expect a greater reduction in ADHD symptoms in children whose parents receive the parent-only intervention compared to the no-intervention (control) arm. This work has public health implications in terms of both the delivery of interventions in 'real-world' settings and in improving children's outcomes.

METHODS AND ANALYSIS

As an early intervention study, we will focus on children in their first 4 years of primary school (ages 4–8 years). The main methodologies consist of a cluster RCT, together with a nested qualitative study. Components include the use of a group programme for parents of children who score high on a measure of hyperactivity/inattention, and the development of an educational package for teachers to enable them to better manage

ADHD-type behaviours in the classroom. This study will consist of three arms; a group programme for parents (parent-only intervention); a group programme for parents and a teacher training package with weekly feedback to the teacher (combined intervention); waiting list control (no intervention). The study will be carried out in 6–12 primary schools in Nottinghamshire, Derbyshire and Lincolnshire. As part of a stepped-care approach in increasing the range of the intervention, the combined intervention will include a teacher educational session covering the strategies used within the parent programme. Weekly updates from the parent groups will also be provided to teachers in the combined intervention. We will measure the cost components of the screening, interventions and other resource inputs and costs as assessed from a societal perspective using a 'bottom-up' ingredients approach. We will also carry out qualitative interviews with participating and non-participating parents, teachers and other key stakeholders to better understand the acceptability and feasibility of the interventions.

A baseline local mapping survey (Coates and Sayal, unpublished observations) evaluated current practice and the availability of groups for parents provided by statutory and voluntary sector services. This highlighted that the '1-2-3 Magic' programme was widely used for children with ADHD-type difficulties. A meeting with local stakeholders (including service organisations who deliver parenting programmes locally) was held to develop consensus on the choice and mode of delivery of a programme for parents of children at risk of ADHD. The stakeholder event confirmed the appropriateness of '1-2-3 Magic'.

Screening and inclusion criteria for main trial

Large primary schools, which have two to three classes per year, will be identified using Department for Education and local authority data. Of these schools, those which have $\leq 20\%$ English as an Additional Language will be invited to participate in order to maximise recruitment rates, as the programme and all materials are presented in English.

Parents of children aged between 4 and 8 years (reception to year 3) will be invited to participate in the study. Written information about the study will be sent to the parents through the school. Parents who wish to participate in the study will be asked to complete and return a consent form and the Strengths and Difficulties Questionnaire (SDQ) which is a well-validated measure of child mental health.²⁰ The SDQ is a commonly used screening questionnaire for ADHD in community settings and has good sensitivity and specificity for identifying probable ADHD.²¹ The scale consists of 25 items, divided into 5 subscales (conduct problems, hyperactivity/inattention, emotional symptoms, peer problems and prosocial behaviours), each of which contain 5 items and are rated on a 3-point scale, 'not true'; 'somewhat true'; 'certainly true'. Conduct problems, hyperactivity, emotional symptoms and peer problem scores

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are summed to generate a total difficulties score. The questionnaire also informs about parent-identified difficulties, impact for the child (an item on distress and four items on social impairment; friendships, classroom learning, home life and leisure activities) and burden for the family.²⁰ There are extensive normative data available, as the SDQ was used to assess the mental health of over 20 000 children in the 1999 and 2004 British Child & Adolescent Mental Health Surveys.^{22 23} Parents of children scoring ≥ 6 (cut-off identifying approximately the top 20%) on the hyperactivity/inattention subscale of the SDQ (high-scoring children) will be eligible for entry into the main trial.

To provide information on pervasiveness of symptoms across settings, teachers will also be asked to complete the Teacher SDQ for all high-scoring children and matched (by gender and school class where possible) low-scoring children where parental consent has been received. As teachers are not being asked to complete questionnaires on every child in the class, this approach will minimise teacher burden and enable blinding at the teacher level, that is, teachers will be asked to complete questionnaires on an equal number of high and low scorers.¹² Teachers will not be informed which children are high and low scorers on the parent SDQ.

Main trial

Parents of children who meet the inclusion criteria (high scorers on the parent-rated SDQ) will be invited to participate in the main study. Participating schools will be randomised into 1 of 3 arms (see below). The intervention that parents will be offered will depend on which arm the child's school has been randomised to. Both parent-rated and teacher-rated baseline and outcome measures will be collected (see the section Measures below).

Interventions

Arm 1—Combined intervention: parents will be invited to take part in a three-session group parent programme based on '1-2-3 Magic', held at or near their child's school. The sessions will cover a set of strategies that parents can use to encourage behaviour they want their child to 'start', a counting method strategy to help stop unwanted behaviours and ways to help parents build a positive relationship with their child. Each session will last for approximately 1.5 h.

Teachers will receive an educational training package that covers the strategies being discussed with the parents. This will comprise a session, over approximately 1.5 h, presenting the principles of the '1-2-3 Magic' programme and will take place in the same week that the first parent group programme starts. This will be followed by the provision of brief handouts each week for 3 weeks, containing the information being conveyed to parents in their sessions.

Arm 2—Parent-only intervention: parents will be invited to take part in a three-session group parent programme as described above.

Arm 3—No intervention (control arm): the parents will be offered the group parent programme after the 6-month follow-up data have been collected.

Measures

Primary outcome (completed at baseline, 3-month and 6-month follow-up—the primary outcome time point is 6 months after baseline): the short version of Conners' Parent and Teacher Rating Scales Revised has items mapping onto four scales (hyperactivity, cognitive problems/inattention, oppositional behaviour and an ADHD index), which provide age-standardised and gender-standardised T-scores (mean=50; SD=10).²⁴ Separate versions are available for completion by parents and teachers.

Secondary outcomes

- Changes in parental burden (from the SDQ). The parent SDQ will be completed at baseline, 3-month and 6-month follow-up.
- Changes in parental mental health (using the Malaise inventory).²⁵ The Malaise inventory will be completed at baseline, 3-month and 6-month follow-up.

Other measures

- EQ-5D-Y: child health-related quality of life will be assessed using a utility questionnaire completed by parents at baseline, 3-month and 6-month follow-up.²⁶ The EQ-5D-Y is a child-appropriate version of the EQ-5D, a generic preference-based measure of health-related quality of life.²⁷ The use of the EQ-5D-Y allows for the comparison of interventions across a wide range of comparable dimensions and can therefore be used to perform a cost-utility analysis.
- Child Health Utility 9D (CHU9D): child health-related quality of life will also be assessed using this parent-rated questionnaire completed at baseline, 3-month and 6-month follow-up.²⁸ The CHU9D is a generic preference-based measure of health-related quality of life that has been developed with children, rather than being an adjusted version of an adult measure. Both the EQ-5D-Y and CHU9D have satisfactory validity and reliability,²⁹ though we expect that the CHU9D might be a more valid and reliable measure to use in relation to younger children.
- Resource cost of the study will be measured using an adapted version of the Client Service Receipt Inventory (CSRI)³⁰: we will use the version of the CSRI that has previously been adapted for use for children with ADHD-type problems.³¹ This collects information on all the services and supports used by the child and enables support and family borne costs to be estimated. This version of the CSRI has been further adapted to give estimates using the wage rate, where possible, of indirect cost incurred by the child's parents or carers. The CSRI will be administered at baseline, 3-month and 6-month follow-up. Administering the CSRI every 3 months minimises problems with participant recall.

The inclusion of these clinical, utility and cost measures at baseline and follow-up will enable cost-effectiveness and cost-utility analyses to be carried out (see below).

Sample size and justification

The effects sizes detected will inform the sample size required for a future definitive cluster RCT. The sample sizes estimated here should be considered as guidance for designing a further larger RCT. Sample size calculations are based on a three-group (parent and teacher; parent; and control) one-way analysis of variance, assuming that the three-group means are evenly spread out, with equal allocation to each group.³² On the basis of a large effect size (0.8) between any two groups and clustering (allowing for an intraclass correlation (ICC) of 0.05 with 12 subjects per school) at the school level, the sample size calculation for a power of 80% and significance level of 0.05 indicates that approximately 150 parents need to participate. For a definitive cluster RCT, we will require a minimum of 12 participating schools. On the basis of average class sizes of 30 and two classes per year, we estimate that parents of 240 children in each school will be invited to complete screening questionnaires. With an anticipated response rate of 50% (following the use of reminder questionnaires to non-respondents) and a cut-off set to pick up the highest scoring 20%, we expect to identify 24 high-scoring children per school. These parents will be invited to participate in the interventions. Through the use of reminder invitations (using the contact details that parents have provided), we anticipate collecting follow-up data (assuming an intention-to-treat analysis) from 50% (12 per school) of invited parents.

Randomisation and blinding

Once recruited, each school will be randomised by the Clinical Trials Unit at The University of Nottingham to one of the three arms using a block randomisation procedure. Although it is not possible to blind trial participants or researchers delivering the interventions, outcome measures will be obtained by parent or teacher self-completed questionnaires. Outcome assessors for the CSRI and the trial data analysts will be blinded to school intervention status.

Data analysis plan

Analysis will follow the principle of intention-to-treat. Descriptive analysis will be carried out to present means and variance of the primary and secondary outcomes for each group at baseline and 6-month follow-up separately, by subscale of the primary outcome if necessary. Missing outcome data and possible associations will be examined using logistic regression analysis. Multiple imputations of missing data using the Markov Chain Monte Carlo method will be considered where appropriate. The 3-month measurements will be used to inform multiple imputations of missing data for the primary outcome at 6 months and can be used to examine for

difference in changes of the outcome measure between the arms. For mean efficacy of the interventions for the primary outcome, two-level regression models for data with nested structure (children within schools in this case) will be used. The differences between groups will be estimated as fixed effects, with adjustment for baseline measures and other potential covariates in the model. The school ICC will be estimated based on the variance components of the two-level models. To examine intervention effects on the subscale level of the primary outcome, we shall use multivariate multilevel models to examine the four subscales simultaneously, taking into account the nested structure and correlation between subscales.

For secondary outcomes, the same two-level regression models will be used, with changes from baseline to 6-month follow-up as the dependent variable. Variable transformation might be considered before fitting two-level regression models if the distribution of the change variable is skewed.

Economic analysis

A cost-effectiveness and cost-utility analysis of the interventions will be performed. The children's version of the CSRI will be used to track the personal, societal and health service resource usage in the different groups in each of the three study arms.³⁰ Information gathered at the 3-month and 6-month follow-ups will measure the change in resource use across all three arms over the period from the start of the intervention to the end of the follow-up period. A cost-effectiveness analysis will be performed in relation to changes in the ADHD index of the parent-completed Conners' Rating Scales Revised. A cost-utility analysis will be performed using the EQ-5D-Y and CHU9D.

The study will seek to use a number of routine health service costs where possible. Primary care costs will be attributed using data from the Personal Social Services Research Unit, Unit Costs of Health and Social Care.³³ Any drug costs will be taken from the British National Formulary. Staff costs, where not available in Curtis,³⁴ will be taken directly from the employers records. An average cost per intervention will thus be attributed based on staff and sessions. Family borne costs will be collected retrospectively for the previous 3 months using the CSRI. The resource cost of running each of the interventions will be included. These will include capital costs (eg, rooms and overheads), consumables and staff time including teachers' time and parents' time. Where possible, if appropriate, the parent time will be calculated by any lost earnings and average wage rate. Where this is not obtained, an average time cost may be substituted for parent time based on percentage attribution of average wage rate to give a leisure time rate.

Health-related quality-of-life data, as recorded by the EQ-5D-Y and CHU9D, will be used in conjunction with published valuation studies to calculate quality-adjusted life years (QALYs), enabling a cost-utility analysis to be

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completed. In addition, the cost-effectiveness of each intervention arm, compared with the no-intervention arm, will be estimated in terms of the Conners' Rating Scale. The incremental cost-effectiveness ratio will be generated comparing the combined intervention to the parent-only intervention to the no-intervention arm. Cost-effectiveness acceptability curves (CEACs) will be generated to explore the likelihood that the combined intervention is more cost-effective than the parent-only intervention and the no intervention arms, as measured by the Conners' Rating Scale, if different monetary values are attached to this fall in reduction of ADHD symptoms. The net benefit method³³ will be used to construct the CEAC where net benefit (NB)=($\lambda \times E$) - C (λ =monetary value that society places on one unit reduction in the Conners' Rating Scale score, E=reduction in Conners' Rating Scale score associated with the intervention and C=costs) and a range of values for λ are assumed. Cost data and cost-effectiveness data are frequently skewed and as a result, economic evaluation can be misleading if average costs are skewed by extreme outliers. In this event, the distribution of the data will be examined by employing bootstrapping. Sensitivity analyses, based on key assumptions that emerge from the analysis of contextual factors will be explored in terms of their cost utility and cost-effectiveness.

ETHICS AND DISSEMINATION

The study received ethical approval from The University of Nottingham Medical School Ethics Committee (C/07/2010) and is currently recruiting participants. The aim of this project is to test the feasibility of delivering an early intervention programme through schools and its local implementation in practice, with qualitative and quantitative evaluation. Results from the study will show whether group programmes for parents of children at risk of ADHD are effective and feasible. As part of a stepped-care approach, we will examine whether the updates from the weekly parent groups are put into practice within the school setting and result in additional improvements as well as exploring potential mediators of any improvement. Although follow-up is limited to the short term (6 months), there may be longer-term effects on costs and outcomes. If the feasibility of the delivery of such interventions can be demonstrated, future studies will be able to investigate longer-term cost-effectiveness.

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Contributors KS and CH conceived the study, KS wrote the project application for funding and all authors contributed to the development of the study protocol. All authors contributed to the drafting of the manuscript or

revising it critically for important intellectual content. All authors read and approved the final manuscript.

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Competing interests None.

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